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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/786,429
Filing Date: February 25, 2004
Appellant(s): BUCKEY ET AL.

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For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 2008 appealing from the Office action mailed July 14, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

Uneno et al., Life Science, 1988, vol. 43, pp 413-420

Abstract of Kohl et al., Aviat Space Environ Med., 1991, Vol. 62, no. 5, pp 392-396

Abstract of Weinstein et al. Aviat Space Environ Med., 1997, vol. 68, no. 10, pp 890-894

British Medical Journal, Feb 1970, pages 481-483

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueno in view of Drug Information Handbook, BMJ (British Medical Journal, Feb 1970, pages 481-483), Weinstein et al., Abstract of Aviat Space Environ Med, 1997;68(10):890-894, and Kohl et al., abstract of Aviat Space Environ Med, 1991,;62(5):392-396, Ueno and Drug Information Handbook are references of record.

Ueno et al. teaches treatment of S. murinus by administering 20mg/kg of chlorpheniramine in treating motion sickness (see the abstract).

Ueno et al. does not expressly teach the dosage of chlorpheniramine as 12mg. Ueno et al. does not expressly teach chlorpheniramine as administered orally.

Drug Information Handbook teaches the human dosage of chlorpheniramine as 8-12mg every 8-12 hours (See the usual dosage section).

BMJ teaches various antihistamine are useful orally to treat vomiting, which is a symptoms of motion sickness (See Table 1, page 483).

Weinstein et al. teaches common pharmacological agents for treating symptoms of motion sickness in the U.S. are over-the-counter antihistamines and they are orally administered.

Kohl et al. teaches oral terfenadine as effective in treating motion sickness.

It would have been obvious to one of ordinary skill in the art at the time of invention to employ chlorpheniramine orally in a dosage of 12 mg in a method of treating motion sickness.

One of ordinary skill in the art would have been motivated to employ chlorpheniramine orally in a dosage of 12 mg in a method of treating motion sickness. The human dose of chlorpheniramine encompasses the dosage herein claimed. Furthermore, other various known anti-histamines are often administered orally when treating motion sickness as evidenced by BMJ, Weinstein et al. and Kohl et al. Thus, administering chlorpheniramine, also an anti-histamine, orally to treat motion sickness would be obvious. Therefore, possessing the teachings of the cited prior art, one of ordinary skill in the art would employ the old and well known compound,

chlorpheniramine, in a dosage of12 mg, orally in the method of treating symptoms of motion sickness.

(10) Response to Argument

Appellant's arguments in the Brief filed September 10, 2008 averring the dosage claimed as being 2-order of magnitude lower than that of Ueno are not convincing. It is true that Ueno teaches a dosage of chlorpheniramine as 20mg/kg, but it is **not** a human dose. The dose of chlorpheniramine taught in Ueno is for Suncus Murinus (Shrews). It is not clear how the appellant can simply extrapolate the dose from shrews to human. There is no information provided by the appellant with regards to inter-specie dosing variation between human and shrews. The examiner notes that human dose of chlorpheniramine is well established (See the Drug Information Handbook). The maximum adult dosage for chlorpheniramine as an antihistamine (for any indication) is 24mg/day (oral) or 40mg/day (parenteral), which is much less than the dosage for Suncus Murinus. From this information alone, it is clear to one of ordinary skill in the art that the appellant's way of extrapolation for dosage for chlorpheniramine from shrews to human is incorrect. Rather, one of ordinary skill in the art would employ the well-establish antihistamine dosage of chlorpheniramine in the method of treating symptoms of motion sickness. Furthermore, the shrews used in Ueno experiment only weigh 40-70g (0.04-0.07 kg). The dosage used will be approximately 1 - 1.4mg. It is clear that the alleged "2-order magnitude" of dosage by appellant is incorrect.

Appellant's arguments in the Brief filed September 10, 2008 averring the different routes of administration being claimed as opposed to what is taught in Ueno are not

convincing. The examiner notes that oral antihistamine in general has been recognized in the art as being useful in treating vomit and nausea (see British Medical Journal [BMJ] reference). Therefore, absent evidence to the contrary, possessing the teachings of the cited prior art, one of ordinary skill in the art would employ chlorpheniramine, either orally or subcutaneously, in treating symptoms of motion sickness. The examiner notes that chlorpheniramine is active both orally and subcutaneously.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/San-ming Hui/

Primary Examiner, Art Unit 1617

Conferees:

/Shengjun Wang/

Primary Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617